UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

[UNDER SEAL],	
Plaintiff,	Civil Action: _____
v.	FILED UNDER SEAL PURSUANT TO 31 U.S.C. §3730(b)(2)
[UNDER SEAL],	
Defendant(s).	COMPLAINT UNDER THE FEDERAL FALSE CLAIMS ACT AND VARIOUS STATE FALSE CLAIMS ACTS
	JURY TRIAL DEMANDED

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES *ex rel* J. DOE, STATE OF CALIFORNIA *ex rel* J. DOE, STATE OF FLORIDA *ex rel* J. DOE, STATE OF GEORGIA *ex rel* J. DOE, STATE OF ILLINOIS *ex rel* J. DOE, STATE OF INDIANA *ex rel* J. DOE, STATE OF MICHIGAN *ex rel* J. DOE, STATE OF NEW JERSEY *ex rel* J. DOE, STATE OF NEW YORK *ex rel* J. DOE, STATE OF NORTH CAROLINA *ex rel* J. DOE, STATE OF TEXAS *ex rel* J. DOE, COMMONWEALTH OF VIRGINIA *ex rel* J. DOE, v. AMGEN, Inc., Defendants.	Civil Action: _____ FILED UNDER SEAL PURSUANT TO 31 U.S.C. §3730(b)(2) COMPLAINT UNDER THE FEDERAL FALSE CLAIMS ACT AND VARIOUS STATE FALSE CLAIMS ACTS JURY TRIAL DEMANDED

INTRODUCTION

1. Relator, J. Doe, brings this action under the federal False Claims Act, as amended, 31 U.S.C. § 3729 *et. seq.*, as well as various state false claims statutes, and alleges as follows:

2. This is a *qui tam* action brought by J. Doe on behalf of the United States and various States to recover penalties and damages arising from the conduct of Amgen, Inc. (hereinafter "Amgen"). Amgen instituted a misleading off-label marketing campaign designed to induce doctors to prescribe Amgen's drug Neulasta in conjunction with a chemotherapy regimen that did not meet FDA labeling requirements. This complaint, which outlines the details of Amgen's fraudulent and illegal practices, is based upon non-public information J. Doe obtained while employed by Amgen, and J. Doe's personal observation of the acts and conduct described herein.

3. In connection with the filing of this original Complaint, Relator has furnished the United States with substantially all material evidence and information in Doe's possession.

THE PARTIES

4. Relator J. Doe (" Doe ") is a medical doctor and is a citizen of the United States. Doe was employed by defendant. During the course of Doe's

employment, Doe held positions that permitted Doe to acquire direct and personal knowledge of Defendant's fraudulent and illegal practices.

5. Defendant Amgen, Inc., is a pharmaceutical company, with locations in the US, Puerto Rico, the Netherlands, and Ireland. It is incorporated in the State of Delaware, and doing business in the Southern District of New York. Defendant's corporate headquarters are located at One Amgen Center Drive, Thousand Oaks, CA, 91320.

JURISDICTION AND VENUE

6. This is a civil action arising under the laws of the United States, and specifically, 31 U.S.C. § 3729, *et seq*., the "False Claims Act." This Court has jurisdiction over this action pursuant to 31 U.S.C. § 3732 (a) and (b).

7. Venue is proper in this district pursuant to 31 U.S.C. § 3732 (a) because Defendant Amgen transacts business in this district.

FACTUAL BACKGROUND

Neulasta

8. Neulasta, developed and marketed by Amgen, was first approved by the FDA in 2002. In 2005, an expanded indication was approved by the FDA, expanding the number and type of chemotherapy regimens for which Neulasta was indicated.

9. Neulasta is one of the top ten drugs paid for by Medicare. In 2010, it constituted 5.2% of total Medicare expenditures.

10. Neulasta is given via subcutaneous injection (under the skin), and is administered once per chemotherapy cycle.

11. Chemotherapeutic drugs work by targeting and killing cells that have an abnormally high rate of growth and division. Although this is effective in killing off rapidly dividing cancer cells, it also can target and kill normal bone marrow cells, since they too divide rapidly. This is a significant complication with the use of chemotherapeutic drugs, because bone marrow produces various types of blood cells, including white blood cells that are important in fighting infection.

12. Neulasta is the brand name for pegfilgrastim injection, developed and marketed by Amgen. Neulasta is part of a class of drug known as "granulocyte colony stimulating factors" (G-CSF). G-CSFs stimulate proliferation of different types of blood cells. Neulasta specifically stimulates bone marrow to produce a type of white blood cell known as a "neutrophil," to offset the destructive effects of chemotherapy.

13. Neutrophils are the most abundant type of white blood cell. They are found in the bloodstream and normally are the first responders when there is acute

inflammation caused by infection, environmental exposures, or certain types of cancer. An abnormally low neutrophil count is called "neutropenia."

14. The Cancer Therapy Evaluation Program (CTEP), a division of the National Cancer Institute (NCI), has created and published Common Toxicity Criteria (CTC).

15. Based on the CTC, neutropenia can be classified into three different levels, based on absolute neutrophil count (ANC): mild (ANC 1000-1500), moderate (ANC 500-1000) (also known as "Grade 3 neutropenia"), and severe (ANC below 500) (also known as "Grade 4 neutropenia").

16. A low neutrophil count accompanied by fever is called "febrile neutropenia (FN)." Both Grade 3 neutropenia accompanied by fever and Grade 4 neutropenia are known as febrile neutropenia.

17. Neulasta was originally approved by the FDA in 2002 as a treatment for patients with non-myeloid malignancies (i.e. cancers not affecting or involving bone marrow), who were undergoing chemotherapy.

18. Neulasta was specifically intended for patients receiving myelosuppressive chemotherapy drugs (those that reduce the number of bone marrow cells), and was approved as a prophylactic treatment to decrease the incidence of febrile neutropenia. The FDA approved Neulasta for patients

undergoing chemotherapy regimens that had a greater than 30-40% risk of febrile neutropenia (FN).

19. In 2005, the FDA approved an expanded indication for Neulasta based upon a randomized Phase III clinical trial. This trial showed that Neulasta was effective in protecting patients undergoing moderately myelosuppressive chemotherapy from infection (as manifested by febrile neutropenia), when it was administered in the first cycle of chemotherapy. The study showed that administering Neulasta in the first cycle of chemotherapy decreased FN incidence by 94% (1% FN incidence vs. 17% FN incidence with placebo).

20. The label was therefore expanded to include patients that had at least a 17% risk of FN.

AMGEN'S OFF-LABEL MARKETING OF NEULASTA

21. Soon after the FDA approved the expanded label, Amgen launched a marketing campaign that promoted the use of Neulasta in patients with breast cancer who were receiving a particular type of chemotherapy known as the adriamycin-cyclophosamide AC regimen.

22. The AC regimen is a chemotherapy regimen that consists of two chemotherapeutic agents, adriamycin (doxorubicin) and cyclophosamide; both are

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given once every 3 weeks for 4 cycles. It is commonly used as an adjuvant therapy (i.e. administered after surgery to reduce the risk of recurrence).

23. According to the American Cancer Society, the AC regimen is one of the most common chemotherapy regimens; it currently encompasses 15% of the market.

24. Amgen promoted the use of Neulasta during the first cycle of treatment with the AC regimen by falsely claiming that the AC regimen had a 17% risk of FN.

25. Amgen claimed to base this on a 2003 study by Dr. I. Craig Henderson, which was presented to the FDA's Oncology Drugs Advisory Committee (ODAC). Henderson's study was conducted by the CALGB (Cancer and Leukemia Group B) cooperative group, a national clinical research group sponsored by the National Cancer Institute (NCI). CALGB receives funding from the NCI, NIH and HHS. This study investigated the AC regimen followed by Taxol; one of his findings was that the *infection rate* for the AC regimen alone was 17%. A 17% *infection rate* however, is not equivalent to a 17% risk of FN, because not all infections lead to FN.

26. The studies evaluating the AC regimen show that on average, the FN risk for AC regimen is between 0-3%. Only one small study of 50 patients with

metastatic breast cancer showed a risk as high as 13%. No studies show a risk greater than 13%. (See Appendix A.)

27. The risk of FN in patients treated with the AC regimen alone does not come close to 17%. In fact, the AC regimen had a significantly *lower* risk of FN compared to other protocols against which it was tested.

28. Amgen nevertheless persisted in marketing Neulasta to patients receiving AC only, which it knew was based solely on a misleading reading of the 2003 Henderson study.

29. In 2005, after the FDA approved the expanded label for Neulasta, there was a meeting of all the Neulasta teams.

30. At this meeting, a 2003 Amgen sponsored study by Lodovico Balducci was discussed. The study recommended prophylactic treatment with G-CSFs for all patients over the age of 70 regardless of the risk of FN. This study (published in 2007) can be considered a seeding trial.

31. Seeding trials are also known as marketing trials. A seeding trial is a clinical trial whose primary purpose is to raise physicians' awareness of a certain drug or intervention, as opposed to proving a scientific hypothesis. Seeding trials tend to have low clinical or scientific value. See Kessler DA, Rose JL, Temple RJ

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Schapiro R. Griffin JP (November 1994). "Therapeutic-class wars - drug promotion in a competitive marketplace". *N. Engl. J. Med*, 331 (20): 1350-3.

32. The Balducci study looked at two groups of patients, one of which was receiving prophylactic GCSF, and one of which was receiving reactive GCSF (after symptom onset). However, with the exception of lymphoma patients on the CHOP regimen, none of the chemotherapy regimens tested had a risk of FN that was higher than 17%. For example, The AC patients in the control group in this study had a FN incidence rate of 10%. Therefore the utility of this study in identifying patients appropriate for Neulasta prophylaxis is limited, since the majority of patients in the study would not meet the requirements of the label.

33. Balducci also published a paper on the same subject in 2003, in which he recommended GCSF prophylaxis for elderly patients. Much of the basis for this recommendation was the NCCN guidelines, which were developed using data from lymphoma patients on the CHOP (cyclophosamide, doxorubicin, vincristine, and prednisone) regimen. Both lymphoma and the CHOP chemotherapy regimen have a risk of FN which is significantly higher (i.e., over 17%) than the risk of FN for patients on the AC regimen. In addition, the 2000 ASCO GCSF guidelines cited by Balducci do not specifically recommend that all patients over the age of 70 be given primary prophylaxis with GCSFs. They simply state that "special"

patients, which include those receiving particularly toxic chemotherapy regimens, or extensive radiation, or those with significant co-morbidities may benefit from prophylactic GCSF use. Age alone is not a determinative factor. The 2001 SIOG paper discussed by Balducci also cites the NCCN guidelines for prophylactic GCSF usage, which, as above, were based on the CHOP regimen in lymphoma patients, both of which have a significantly higher FN risk than that of breast cancer patients on the AC regimen. See Balducci et. al., 2003.

34. During discussion of the Balducci study, the Henderson study was also brought up by Mike Hale, a member of the US brand/marketing team, who claimed that this study showed a 17% risk of FN for AC regimen patients.

35. Hale argued that marketing Neulasta to these patients would open up a large patient pool.

36. Relator repeatedly warned Lyndah Dreiling, the Medical Director for Neulasta, that this marketing position was misleading. Relator also brought up at team meetings that the Henderson article did not support Amgen's claims because Henderson discussed only an *infection rate* and not the risk of FN.

37. At one such meeting, which took place in August or September 2005, shortly before all the Neulasta marketing and promotional materials were printed, Relator was told by Neil Lambert, the Neulasta Promotions Lead, that he and

Dreiling had called Dr. Henderson directly, and that Dr. Henderson had confirmed that his reference to infection rate meant neutropenia.

38. Relator was skeptical of this claim. Relator looked up Henderson's presentation to ODAC that clearly showed that Henderson himself found that the FN or patients on the AC regimen was <1%, not 17%, with an incidence of infection rate in neutropenic patients of 5%.

39. Relator sent to Dreiling Henderson's slides showing that FN incidence was only 1%, and infection rate was 5%, but received no response.

40. On June 26-28, 2006, Relator attended a meeting in Zug, Switzerland. This meeting was the global summit offsite meeting for the Neulasta Global Commercial Team. The goal of this meeting was to align marketing strategy across markets. Relator stressed to Lyndah Dreiling prior to this meeting that Neulasta was not appropriate for use in the AC regimen. Relator re-sent Dreiling slides from Henderson's ODAC presentation in an attempt to show her how the study was being misinterpreted by Amgen. Dreiling never responded to Relator despite these repeated attempts to send her the Henderson Slides. Dreiling never acknowledged to Relator that she had received or reviewed the slides, and never acknowledged Relator's concerns.

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41. Relator also participated in multiple team meetings in 2006 with the Medical Affairs team. At these meetings, Relator brought up the erroneous interpretation of the infection rate, and stressed that the AC regimen did not fit the expanded indication for Neulasta. Relator's comments were ignored.

42. Relator consistently complained about Amgen's misleading marketing of Neulasta based on false data. On average, Relator would discuss the matter twice a month at various meetings with different Amgen teams.

43. Despite these efforts, nothing was done to correct the misleading statements, and Amgen continued to actively promote Neulasta as a first line preventative treatment for patients receiving the standard AC regimen.

44. In late 2006, US Oncology, a nationwide network of community-based oncology physicians, expressed their frustration with Amgen's continued practice of promoting Neulasta for use with the AC regimen.

45. US Oncology provides management services for individual or small group physician practices and 20% of cancer patients are treated in one of their practices. Among the services US Oncology provides is drug procurement. It is one of the largest purchasers of Neulasta. In 2006, US Oncology was in the process of creating new "Pathways." These Pathways would indicate to physicians which drugs to prescribe based on certain diagnoses.

46. US Oncology's placement of Neulasta on a Pathway for a particular chemotherapy regimen is a stronger endorsement than a simple recommendation. If a doctor at US Oncology wants to deviate from the Pathway, he/she must have a colleague sign the order as well (2 physician signatures are required to override a Pathway). US Oncology was working on creating pathways for which chemotherapy regimens were appropriate for G-CSF use.

47. Because research indicated that FN risk for the AC regimen was only 3%, US Oncology did not believe that it was appropriate to recommend Neulasta for use with the AC regimen, as this use would not be consistent with the FDA label.

48. To convince US Oncology that the AC regimen had a 17% or greater risk of FN and was therefore appropriate for preemptive Neulasta usage, a team from Amgen, including the Relator, Tim Walker (brand director for Neulasta), and Lyndah Dreiling met with US Oncology on July 11, 2006.

49. William Thames, National Account Director--Market Focus, Nicky Dozier, Director of Drug Management, and Kathy Lokay, Senior Vice President, were the key US Oncology people present at this meeting.

50. Relator's opposition to this position was well known to Walker and Dreiling but Amgen still wanted her presence at the meeting.

51. Relator did not make any part of Amgen's presentation. Relator believes that Amgen's purpose in requiring Relator to be present was to create 'window dressing' -- intended to lend credibility to Amgen's argument despite overwhelming evidence that actual FN risk for the AC regimen was around between 0-13% and hovered around 6%. In addition, Relator's most recent research had been on the cost effectiveness and economics of Neulasta treatment. Because US Oncology is one of the largest purchasers of Neulasta, it received a volume-based discount from Amgen. US Oncology was concerned that because they were no longer recommending Neulasta for use with the AC regimen, they would be penalized financially. Relator believes another reason she was brought to the meeting was to help assuage these concerns.

52. Despite Amgen's efforts, US Oncology remained unconvinced, and stated that the data did not support Amgen's claims.

53. Dozier in particular specifically stated that neither the literature, nor US Oncology's own data supported Amgen's claims.

54. To bring to light the correct FN risk for the AC regimen, US Oncology conducted a poster session at the San Antonio Breast Cancer Symposium, on December 14-17, 2006.

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55. A poster session is the presentation of peer-reviewed research information by representatives of a research team at an academic or professional conference.

56. Dr. Frankie Ann Holmes, a medical oncologist with US Oncology, was particularly upset about Amgen's claims that Neulasta was appropriate for use in the AC regimen. She was the driving force behind pulling together the US Oncology data that countered Amgen's claims and submitted a poster to the San Antonio conference.

57. US Oncology's poster highlighted the fact that the actual FN risk for the AC regimen was 3-4%, 6% in dose dense regimens -- putting this regimen well below the 17% threshold for which prophylactic use of a G-CSF was indicated. Although a poster session does not involve a formal presentation in a room reserved for that purpose, a poster session may reach as many or more scientists who walk into the area where the poster has been installed, listen to the research team, interact with the researchers, and ask questions about the research.

58. Shortly after this meeting, in December 2006,Amgen quietly ended the AC regimen campaign and stopped actively promoting Neulasta for use in AC only patients.

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59. Amgen never publicly corrected its prior misleading claims regarding the FN risk in the AC regimen.

60. Amgen continued to promote Neulasta for use in regimens with a "moderate" risk of FN. Amgen defined the term "moderate" as a FN risk of 17-30%. However, this was confusing terminology as the National Comprehensive Cancer Network (NCCN) has published widely used guidelines defining "intermediate" FN risk as 10-20%.

61. Amgen's subtlety and delay in withdrawing its AC campaign, coupled with its continued misleading use of language, led to a 10% increase in Neulasta market share per year; most of this is for off-label use.

PERTINENT FEDERAL LAWS AND REGULATIONS

Off Label Marketing

62. The dissemination of information on off-label drugs must meet certain requirements. Foremost is that the off-label information must not be misleading.

63. 21 U.S.C. § 360aaa also restricts the conditions under which a manufacturer may disseminate information concerning the safety, effectiveness, or benefit of a use not described in the approved labeling only. This may only be done if:

(1) there is an application filed pursuant to 21 U.S.C. 355;

(2) the information meets the requirements of section 21 U.S.C. § 360aaa-1[1]

(3) The information is not derived from clinical research conducted by another manufacturer or permission has been given to use such information;

(4) the manufacturer has, within 60 days before dissemination submitted to the Secretary (A) a copy of the information to be disseminated; and (B) any clinical trial information relating to the safety or effectiveness of the new use;

(5) the manufacturer has complied with section360aaa-3[2] of this title; and

(6) along with the information on the new use, the manufacturer includes a statement disclosing

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[1] This section sets out that the information must be: (1) an unabridged; (A) peer-reviewed article that was published in a scientifically sound medical journal (defined by 21 U.S.C. § 360aaa-5(5)); or (B) a reference publication that is scientifically sound and (2) is not false or misleading and would not pose a significant risk to the public health. Also, a reference publication is defined as a publication that (1) has not been written, edited, excerpted, or published specifically for, or at the request of, a manufacturer of a drug; (2) has not been edited or significantly influenced by such a manufacturer; (3) is generally available in bookstores, not just through the manufacturer; (4) does not focus on any particular drug of a manufacturer that disseminates information under section 360aaa of this title and does not have a primary focus on new uses of drugs that are marketed or under investigation by a manufacturer; and (5) is not false or misleading.

[2] This section sets forth the requirement that a manufacturer submit a supplemental application for a new use along with progress reports and details about the study.

> (A) (I) that the use is not approved,
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> (ii) that the information is being disseminated at the manufacturer's expense,
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> (iii) the names of the authors who have received compensation from the manufacturer,
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> (iv) the official labeling for the drug,
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> (v) a statement that there are products or treatments that have been approved for the use,
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> (vi) identification of any person that provided funding for the research, and
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> (B) a bibliography of other articles that have been published about the use of the drug.

64. A failure to comply with 21 U.S.C. § 360aaa means that the drug is "misbranded." Although physicians are free to prescribe a drug for an off-label use, the Food and Drug Act prohibits distribution of misbranded drugs, including drugs that have been distributed while accompanied by misleading literature urging doctors to use the drugs in non-approved ways. 21 U.S. C. § 331(a).

65. Whether a drug is FDA-approved for a particular use will largely determine whether a prescription for that drug will be reimbursable under the Medicaid program. Reimbursement by Medicaid is, with only one rare exception, prohibited if the drug is not being used for a medically accepted indication. 42

U.S.C. § 1396r-8(k)(3), Subsection (k)(6) goes on to define a medically accepted indication as one which is approved under the Food, Drug and Cosmetic Act.

66. Basically, once a drug is approved by the FDA for a certain use, it must be promoted by the manufacturer for that use – not for a use that would be better financially for the manufacturer, if such promotion is accomplished by misleading physicians.

67. By promoting Neulasta for use with the AC regimen, which clearly did not have a 17% risk of febrile neutropenia, Amgen actively marketed Neulasta off-label in a way that misled the physicians prescribing it.

Medicare

68. The Health Insurance for the Aged and Disabled Program, Title VIII of the Social Security Act, 42 U.S.C. §§ 1395, *et seq*., (hereinafter "Medicare"), is a health insurance program administered by the Government of the United States and funded by taxpayer revenue.

69. Medicare is overseen by the United States Department of Health and Human Services through its Center for Medicare and Medicaid Services ("CMS").

70. Medicare was designed to be a health insurance program and to provide for the payment of hospital services, medical services and durable medical

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equipment to persons over sixty-five (65) years of age, and for certain others that qualify under the terms and conditions of the Medicare Program.

71. Payments made under the Medicare Program include payment for certain prescription drugs used during treatment at an appropriate medical facility as well as certain drugs injected in a doctor's office (Part B benefit).

72. Pursuant to the Medicare Prescription Drug Improvement and Modernization Act of 2003, effective January 1, 2006, Medicare Part D took effect, extending outpatient prescription drug coverage to all Medicare eligible persons who choose to participate in Part D.

73. Reimbursement for Medicare claims is made by the United States through CMS, which contracts with private insurance carriers to administer and pay claims from the Medicare Trust Fund. 42 U.S.C. § 1395u. In this capacity, the carriers act on behalf of CMS.

74. Neulasta is primarily covered under Part B, although it can be covered under part D in certain circumstances.

Medicaid

75. Through CMS, HHS also administers the Medicaid Program, which provides health care benefits for certain groups, including the poor and the

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disabled, and which is funded in part from federal funds and in part by the state where the provider is located. 42 U.S.C.A. § 1396, *et seq*.

76. State Medicaid programs provide coverage for prescription drugs purchased for Medicaid beneficiaries through their State Plans. 42 U.S.C. § 1396(d)(a)(12). Drugs purchased by Medicaid beneficiaries account for roughly 10% of all prescription drugs purchased in the United States.

The False Claims Act

77. The False Claims Act ("FCA"), 31 U.S.C. § 3729(a)(1)(A), makes knowingly presenting or causing to be presented to the United States any false or fraudulent claim for payment or approval a violation of federal law for which the United States may recover three times the amount of the damages the government sustains and a civil penalty of not less than $5,000 and not more than $10,000 per claim for claims made on or after September 29, 1999.

78. The FCA, 31 U.S.C. § 3729(a)(1)(B), makes knowingly making, using, or causing to be used or made, a false record or statement material to a false or fraudulent claim, a violation of federal law for which the United States may recover three times the amount of the damages the Government sustains and a civil penalty of not less than $5,000 and not more than $10,000 per claim for claims made on or after September 29, 1999.

79. The FCA, 31 U.S.C. § 3729(a)(1)(C)), makes any person who conspires to commit a violation of the FCA liable for three times the amount of damages the Government sustains and a civil penalty of not less than $5,000 and not more than $10,000 per claim.

80. The FCA, 31 U.S.C. § 3729(a)(1)(G), makes any person who knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person.

81. The FCA, 31 U.S.C. § 3729(a)(1)(G) makes any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government," liable for three times the amount of damages the Government sustains, and a civil monetary penalty of not less than $5000, and not more than $10,000 per claim.

82. The FCA defines a "claim" to include any request or demand, whether under a contract or otherwise, for money or property that is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested. 31 U.S.C. § 3729(b)(2).

83. The FCA, 31 U.S.C. § 3729(b)(1) provides that:

> (1) the terms 'knowing' and 'knowingly' – (A) mean that a person, with respect to information – (I) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud.

84. The FCA, 31 U.S.C. § 3729(b)(4) provides that " the term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."

CAUSES OF ACTION
COUNT ONE
FALSE CLAIMS ACT
(31 U.S.C. § 3729)

85. The allegations of paragraphs 1 through 81 are repeated and realleged as though they are set forth herein.

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86. Based on the acts described above, Defendant knowingly violated one or more of the following:

(a) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;

(c) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;

(d) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government.

87. The United States Government unaware of the falsity of these claims, records, and/or statements made by the Defendant and in reliance on the accuracy thereof, paid the Defendant for the claims.

88. Due to the Defendant's conduct, the United States Government has suffered substantial monetary damages.

89. For each violation of the FCA, the United States is entitled to recover treble damages from Defendant. *See* 31 U.S.C. § 3729(a).

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90. In addition, for each violation of the FCA, the United States is entitled to recover from Defendant a civil penalty of not less than $5,500 and not more than $11,000 per false claim or false statement. *Id.;* 64 Fed. Reg. 47099, 47103 (1999).

COUNT TWO
CALIFORNIA FALSE CLAIMS ACT
(Cal Gov't Code § 12651 (a)(1)-(a)(3); (a)(7))

91. The allegations of paragraphs 1 through 81 are realleged as if fully set forth herein.

The California False Claims Act provides, in pertinent part, that:

> (a) Any person who commits any of the following enumerated acts in this subdivision shall have violated this article and shall be liable to the state or to the political subdivision for three times the amount of damages which the state or the political subdivision sustains because of the act of that person. A person who commits any of the following enumerated acts shall also be liable to the state or to the political subdivision for the costs of a civil action brought to recover any of those penalties or damages, and shall be liable to the state or political subdivision for a civil penalty of not less than five thousand dollars ($5000) and not more than ten thousand dollars ($10,000) for each violation:
>
> (1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval.

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> (2) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim.
>
> (3) Conspires to commit a violation of this subdivision.
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> . . .
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> (7) Knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to the state or any political subdivision, or knowingly conceals or knowingly and improperly avoids, or decreases an obligation to pay or transmit money or property to the state or any political subdivision. Cal. Gov't. Code § 12651.
>
> (b) For purposes of this article:
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> (2) "Knowing" and "knowingly" mean that a person, with respect to information, does any of the following:
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> (A) Has actual knowledge of the information.
>
> (B) Acts in deliberate ignorance of the truth or falsity of the information.
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> (C) Acts in reckless disregard of the truth or falsity of the information. Proof of specific intent to defraud is not required. Cal. Gov't. Code § 12650.

92. As set forth herein, Defendant has violated the California False Claims Act in of Cal. Gov't. Code §§ 12651(a)(1), 12651(a)(2), 12651(a)(3), and 12651(a)(7).

93. For each violation of the California False Claims Act, California is entitled to recover treble damages from Defendant. *See* Cal. Gov't. Code § 12651(a).

94. In addition, for each violation of the California False Claims Act, California is entitled to recover from Defendant a civil penalty of up to $10,000.00 per false claim. Id.

COUNT THREE
CLAIMS OF THE STATE OF FLORIDA
VIOLATION OF THE FLORIDA FALSE CLAIMS ACT
(§§ 68.081-.092, FLORIDA STATUTES)

95. The allegations of paragraphs 1 through 81 are realleged as if fully set forth herein.

> Fla. Stat. 68.082(2) provides liability for any person who (a) knowingly presents, or causes to be presented, to an officer or employee of an agency a false or fraudulent claim for payment or approval; (b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by an agency; (c) conspires to submit a false or fraudulent claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid; (g) knowingly makes uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to an agency...is liable to the state for a civil penalty of not less than $5,500 and not more than $11,000 and for treble the amount of

> damages the agency sustains because of the act or omission of that person.

Further, Fla. Stat. 68.082 (c) provides that:

> "Knowing" or "knowingly" means, with respect to information, that a person: 1.Has actual knowledge of the information; 2. Acts in deliberate ignorance of the truth or falsity of the information; or 3. Acts in reckless disregard of the truth or falsity of the information. No proof of specific intent to defraud is required. Innocent mistake shall be a defense to an action under this act.

96. As set forth herein, Defendant has violated the Florida False Claims Act in Florida Statutes §§ 68.082 (2) (a), 68.082 (2) (b), 68.082 (2) (c), and 68.082 (2)(g).

97. For each violation of the Florida False Claims Act, Florida is entitled to recover treble damages from Defendant. *See* Florida False Claims Act § 68.082 (2).

98. In addition, for each violation of the Florida False Claims Act, Florida is entitled to recover from Defendant a civil penalty of not less than $5,500 and not more than $11,000.00 per false claim. Id.

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COUNT FOUR
CLAIMS OF THE STATE OF GEORGIA
VIOLATION OF THE GEORGIA STATE FALSE MEDICAID CLAIMS ACT
(GEORGIA CODE 49-4-168, et seq.)

99. The allegations of paragraphs 1 through 81 are realleged as if fully set forth herein. This is a claim for treble damages and civil penalties under the Georgia State False Medicaid Claims Act.

100. Section 49-4-168.1.(a) of the Georgia State False Medicaid Claims Act provides in pertinent part as follows:

> Any person who:
>
> (1) Knowingly presents or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program;
>
> (3) Conspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid;
>
> …
>
> (7) Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay, repay or transmit money or property to the State of Georgia, shall be liable to the State of Georgia for a civil penalty of not less than $5,500.00 and not more than $11,000.00 for each false or fraudulent claim, plus three times the amount of damages

> which the Georgia Medicaid program sustains because of the act of such person.

101. As set forth herein, Defendant has violated the Georgia State False Medicaid Claims Act in Georgia Code §§ 49-4-168.1 (a)(1), 49-4-168.1 (a)(2), 49-4-168.1 (a)(3), and 49-4-168.1 (a)(7).

102. For each violation of the Georgia State False Medicaid Claims Act, Georgia is entitled to recover treble damages from Defendant. *See* Georgia State False Medicaid Claims Act § 49-4-168.1(a).

103. In addition, for each violation of the Georgia State False Medicaid Claims Act, Georgia is entitled to recover from Defendant a civil penalty of not less than 5,500 and not more than $11,000.00 per false claim. Id.

COUNT FIVE
CLAIMS OF THE STATE OF ILLINOIS
ILLINOIS FALSE CLAIMS ACT
(§§ 740 ILCS § 175/3(a), et seq.)

104. The allegations of paragraphs 1 through 81 are realleged as if fully set forth herein.

105. Section 3 of the Illinois False Claims Act, 740 ILCS § 175/3, provides in pertinent part:

> (a) Liability for certain acts.
>
> (1) In general any person who: ... (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval, (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G)… (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State;... is liable to the State for a civil penalty of not less than $5,500 and not more than $11,000, plus 3 times the amount of damages which the State sustains because of the act of that person…
>
> (2) A person violating this subsection shall also be liable to the State for the costs of a civil action brought to recover any such penalty or damages.
>
> (b) Definitions. For purposes of this Section, (1) the terms "knowing" and "knowingly": (A) mean that a person, with respect to information: (I.) has actual knowledge of the information; (ii.) acts in deliberate ignorance of the truth or falsity of the information; or (iii.) acts in reckless disregard of the truth or falsity of the information, and (B) require no proof of specific intent to defraud..

106. As set forth herein, Defendant has violated the Illinois False Claims Act §§ 740 ILCS § 175/3(a) (1)(A), 740 ILCS § 175/3(a) (1)(B), 740 ILCS § 175/3(a) (1)(C), and 740 ILCS § 175/3(a) (1)(G).

107. For each violation of the Illinois False Claims Act, Illinois is entitled to recover treble damages from Defendant. *See* 740 ILCS § 175/3(a).

108. In addition, for each violation of the, Illinois False Claims Act, Illinois is entitled to recover from Defendant a civil penalty of not less than 5,500 and not more than $11,000.00 per false claim. Id.

COUNT SIX
LAWS OF THE STATE OF INDIANA
VIOLATION OF THE INDIANA FALSE CLAIMS ACT
(INDIANA CODE 5-11-5.5)

109. The allegations of paragraphs 1 through 81 are realleged as if fully set forth herein.

Pursuant to the Indiana False Claims Act (IC 5-11-5.5-2(b)):

> (b) A person who knowingly or intentionally:
>
> (1) presents a false claim to the state for payment or approval;
>
> (2) makes or uses a false record or statement to obtain payment or approval of a false claim from the state;
>
> ***
>
> (6) makes or uses a false record or statement to avoid an obligation to pay or transmit property to the state;

> (7) conspires with another person to perform an act described in subdivisions (1) through (6);
>
> (8) causes or induces another person to perform an act described in subdivisions (1) through (6); is, except as provided in subsection (c), liable to the state for a civil penalty of at least five thousand dollars ($5,000) and for up to three (3) times the amount of damages sustained by the state. In addition, a person who violates this section is liable to the state for the costs of a civil action brought to recover a penalty or damages.

110. As set forth herein, Defendant has violated the Indiana False Claims Act in Indiana Code §§ IC 5-11-5.5-2(b)(1), IC 5-11-5.5-2(b)(2), IC 5-11-5.5-2(b)(6), IC 5-11-5.5-2(b)(7), and IC 5-11-5.5-2(b)(8).

111. For each violation of the Indiana False Claims Act, Indiana is entitled to recover treble damages from Defendant. *See* Indiana False Claims Act§§ IC 5-11-5.5-2(b).

112. In addition, for each violation of the Indiana False Claims Act, Indiana is entitled to recover from Defendant a civil penalty of at least than $5,000. Id.

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COUNT SEVEN
CLAIMS OF THE STATE OF MICHIGAN
VIOLATION OF THE MICHIGAN MEDICAID FALSE CLAIMS ACT
(§§ 400.603 (1), et seq.)

113. The allegations of paragraphs 1 through 81 are realleged as if fully set forth herein.

114. Section 400.603 of the State of Michigan's Medicaid False Claims Act provides in part:

> (1) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact in an application for Medicaid benefits.
>
> (2) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact for use in determining rights to a Medicaid benefit.
>
> (3) A person, who having knowledge of the occurrence of an event affecting his initial or continued right to receive a Medicaid benefit or the initial or continued right of any other person on whose behalf he has applied for or is receiving a benefit, shall not conceal or fail to disclose that event with intent to obtain a benefit to which the person or any other person is not entitled or in an amount greater than that to which the person or any other person is entitled.
>
> ***

MCL §400.602(f) provides:

> "Knowing" and "knowingly" means that a person is in possession of facts under which he or she is aware or

> should be aware of the nature of his or her conduct and that his or her conduct is substantially certain to cause the payment of a Medicaid benefit. Knowing or knowingly includes acting in deliberate ignorance of the truth or falsity of facts or acting in reckless disregard of the truth or falsity of facts. Proof of specific intent to defraud is not required.

115. As set forth herein, Defendant has violated the Michigan Medicaid False Claims Act §§ 400.603 (1), 400.603 (2), and 400.603 (3)

116. For each violation of the Michigan Medicaid False Claims Act, Michigan is entitled to recover from Defendant a civil penalty of not less than $5,000 and not more than $10,000 plus triple the amount of damages suffered by the State as a result of Defendant's conduct. Michigan Medicaid False Claims Act §400.612(1).

COUNT EIGHT
CLAIMS OF THE STATE OF NEW JERSEY
VIOLATION OF THE NEW JERSEY FALSE CLAIMS ACT
(SENATE NO. 232, SIGNED BY GOVERNOR EFFECTIVE APRIL 15, 2008)

117. The allegations of paragraphs 1 through 81 are realleged as if fully set forth herein.

118. Section 2A:32C-3 of the New Jersey False Claims Act provides in pertinent part:

> A person shall be jointly and severally liable to the State ….if the person commits any of the following acts:
>
> a. Knowingly presents or causes to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false claim for payment or approval;
>
> b. Knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the State;
>
> c. Conspires to defraud the State by getting a false claim allowed or paid by the State.
>
> ***
>
> g. Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State.

119. Pursuant to Section 2A:32C-2 of the New Jersey False Claims Act, "No proof of specific intent to defraud is required."

120. As set forth herein, Defendant has violated the New Jersey False Claims Act§§ 2A:32C-3(a), 2A:32C-3(b), 2A:32C-3(c), and 2A:32C-3(g).

121. For each violation of the New Jersey False Claims Act, New Jersey is entitled to recover treble damages from Defendant. *See* New Jersey False Claims Act§2A:32C-3.

122. In addition, for each violation of the New Jersey False Claims Act, New Jersey is entitled to recover from Defendant a civil penalty of not less than

and not more than the civil penalty allowed under the Federal False Claims Act (31 U.S.C. s.3729 et 37 seq.), as may be adjusted in accordance with the inflation adjustment procedures prescribed in the Federal Civil Penalties Inflation Adjustment Act of 1990, Pub.L.101-410. Id.

COUNT NINE
CLAIMS OF THE STATE OF NEW YORK
VIOLATION OF THE NEW YORK FALSE CLAIMS ACT
(NEW YORK STATE FINANCE LAW, - ARTICLE XIII §§ 187 *et seq*.)

123. The allegations of paragraphs 1 through 81 are realleged as if fully set forth herein.

124. The New York False Claims Act (NY State Finance Law, Ch. 56 of the Consolidated Laws - Article XIII §§187 *et seq*.) provides in pertinent part as follows:

> §189. Liability for certain acts.
>
> 1. Subject to the provisions of subdivision two of this section, any person who:
>
> (a) knowingly presents, or causes to be presented, to any employee, officer or agent of the state or a local government, a false or fraudulent claim for payment or approval;
>
> (b) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

> (c) conspires to commit a violation of paragraph (a), (b), (d), (e), (f), or (g) of this subdivision;
>
> ***
>
> (g) knowingly makes, uses or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state or local government; shall be liable to the states or a local government as applicable, for a civil penalty of not less than six thousand dollars and not more than twelve thousand dollars, plus three times the amount of all damages, including consequential damages, which the state or local government sustains because of the act of that person.

125. Pursuant Section 188(3) of the New York False Claims Act, proof of specific intent to defraud is not required.

126. As set forth herein, Defendant has violated the New York False Claims Act in New York State Finance Law Ch.56, Article XIII §§ 189(1)(a), 189(1)(b), 189(1)(c), and 189(1)(g).

127. For each violation of the New York False Claims Act, New York is entitled to recover treble damages from Defendant. *See* New York False Claims Act§189 (g).

128. In addition, for each violation of the New York False Claims Act, New York is entitled to recover from Defendant a civil penalty of not less than $6000, and not more than $12,000. Id.

COUNT TEN
CLAIMS OF THE STATE OF NORTH CAROLINA
VIOLATION OF NORTH CAROLINA FALSE CLAIMS ACT
(NORTH CAROLINA GENERAL STATUTES §§1-605-1-618)

129. The allegations of paragraphs 1 through 81 are realleged as if fully set forth herein.

130. Section 1-607 of the North Carolina False Claims Act provides in pertinent part as follows:

> (a) Liability. – Any person who commits any of the following acts shall be liable to the State for three times the amount of damages that the State sustains because of the act of that person. A person who commits any of the following acts also shall be liable to the State for the costs of a civil action brought to recover any of those penalties or damages and shall be liable to the State for a civil penalty of not less than five thousand five hundred dollars ($5,500) and not more than eleven thousand dollars ($11,000) for each violation:
>
> (1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval.
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.
>
> (3) Conspires to commit a violation of subdivision (1), (2), (4), (5), (6), or (7) of this section.
>
> ***
>
> (7) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an

> obligation to pay or transmit money or property to the State, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State.

131. As set forth herein, Defendant has violated the North Carolina False Claims Act in North Carolina General Statutes §§ 1-607(a)(1), 1-607(a)(2), 1-607(a)(3), and 1-607(a)(7).

132. For each violation of the North Carolina False Claims Act, North Carolina is entitled to recover treble damages from Defendant. *See* North Carolina False Claims Act §1-607(a).

133. In addition, for each violation of the North Carolina False Claims Act, North Carolina is entitled to recover from Defendant a civil penalty of not less than $5500, and not more than $11,000. Id.

COUNT ELEVEN
CLAIMS OF THE STATE OF TEXAS
VIOLATION OF THE TEXAS MEDICAID FRAUD PREVENTION ACT
(TEXAS HUMAN RESOURCE CODE 36.001 - 36.117)

134. The allegations of paragraphs 1 through 81 are realleged as if fully set forth herein.

135. Section 36.002 of the Texas Medicaid Fraud Prevention Act provides in pertinent part as follows:

A person commits an unlawful act if the person:

(1) knowingly makes or causes to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized;

***

(4) knowingly makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning:

> (A) the conditions or operation of a facility in order that the facility may qualify for certification or recertification required by the Medicaid program, including certification or recertification as: (I) a hospital; (ii) a nursing facility or skilled nursing facility; (iii) a hospice; (iv) an intermediate care facility for the mentally retarded; (v) an assisted living facility; or (vi) a home health agency; or
>
> (B) information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program;

***

(9) knowingly enters into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another person in obtaining an unauthorized payment or benefit from the Medicaid program or a fiscal agent;

***

> (12) knowingly makes, uses, or causes the making or use of a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to this state under the Medicaid program.

136. Pursuant to §36.0011 of the Texas Medicaid Fraud Prevention Act, proof of specific intent to commit an unlawful act under this law is not required.

137. As set forth herein, Defendant has violated the Texas Medicaid Fraud Prevention Act in Texas Human Resource Code §§ 36.002 (1), 36.002(4), 36.002(9) and 36.002(12).

138. For each violation of the Texas Medicaid Fraud Prevention Act, Texas is entitled to recover two times the amount of the payment or the value of the benefit described in Subdivision 1 (i.e. the amount of any payment or the value of any monetary or in-kind benefit provided under the Medicaid program, directly or indirectly, as a result of the unlawful act, including any payment made to a third party §36.052(a)(1)) *See* Texas Medicaid Fraud Prevention Act § 36.052(a)(4.)

139. In addition, for each violation of the Texas Medicaid Fraud Prevention Act, Texas is entitled to recover from Defendant a civil penalty of (A) not less than $5,500 or the minimum amount imposed as provided by 31 U.S.C. Section 3729(a), if that amount exceeds $5,500, and not more than $15,000 or the maximum amount imposed as provided by 31 U.S.C. Section 3729(a), if that amount exceeds $15,000, for each unlawful act committed by the person that

results in injury to an elderly person, as defined by Section 48.002(a)(1), a disabled person, as defined by Section 48.002(a)(8)(A), or a person younger than 18 years of age; or (B) not less than $5,500 or the minimum amount imposed as provided by 31 U.S.C. Section 3729(a), if that amount exceeds $5,500, and not more than $11,000 or the maximum amount imposed as provided by 31 U.S.C. Section 3729(a), if that amount exceeds $11,000, for each unlawful act committed by the person that does not result in injury to a person described by Paragraph (A). Texas Medicaid Fraud Prevention Act § 36.052 (3).

COUNT TWELVE
CLAIMS OF THE COMMONWEALTH OF VIRGINIA
VIOLATION OF VIRGINIA FRAUD AGAINST TAXPAYERS ACT
(VIRGINIA CODE 8.01-216.1 et seq.)

140. The allegations of paragraphs 1 through 81 are realleged as if fully set forth herein.

141. Section 8.01-216.3 of the Virginia Fraud Against Taxpayers Act provides in pertinent part as follows:

> A. Any person who:
>
> 1. Knowingly presents, or causes to be presented, to an officer or employee of the Commonwealth a false or fraudulent claim for payment or approval;
>
> 2. Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth;

> 3. Conspires to defraud the Commonwealth by getting a false or fraudulent claim allowed or paid; or
>
> ***
>
> 7. Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Commonwealth; shall be liable to the Commonwealth for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages sustained by the Commonwealth.

142. As set forth herein, Defendant has violated the Virginia Fraud Against Taxpayers Act in Virginia Code §§ 8.01-216.3(A)(1), 8.01-216.3(A)(2), 8.01-216.3(A)(3), and 8.01-216.3(A)(7).

143. For each violation of the Virginia False Claims Act, Virginia is entitled to recover treble damages from Defendant. *See* Virginia Fraud Against Taxpayers Act8.01-216.3(A).

144. In addition, for each violation of the Virginia False Claims Act, Virginia is entitled to recover from Defendant a civil penalty of not less than $5500, and not more than $11,000. Id.

WHEREFORE, Relator respectfully requests this Court to enter judgment for the United States, Relator, and the States listed above in Counts 2-12, and against Defendant on Counts One through Twelve and order as follows:

//

1. For Count One: An amount equal to three times the loss sustained by the Medicare program, plus penalties of $11,000 for each false claim or statement;

2. For Counts 2-12: The maximum amount of damages and civil penalties as allowed by statute for each State;

3. For all Counts: An award of reasonable attorneys' fees, costs and expenses pursuant to all relevant statutes; and

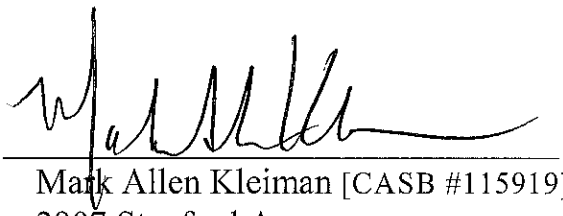
4. For such other and further relief as the Court deems just and proper.

Respectfully submitted,

Respectfully submitted,

Dated: August 7, 2012

LAW OFFICES OF MARK KLEIMAN

BY: 

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Dated: August 7, 2012

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J. DOE

DEMAND FOR JURY TRIAL

Jury trial demanded.

Respectfully submitted,

Dated: August 7, 2012

LAW OFFICES OF MARK KLEIMAN

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Attorneys for Plaintiff/Relator
J. DOE

Appendix A

List of Studies on AC regimen and FN risk--2001-2008

1. Fumoleau et al: Intensification of Adjuvant Chemotherapy: 5-Year Results of a Randomized Trial Comparing Conventional Doxorubicin and Cyclophosphamide (AC) With High-Dose Mitoxantrone and Cyclophosphamide With Filgrastim in Operable Breast Cancer With 10 or More Involved Axillary Nodes. Journal of Clinical Oncology, 19(3), 2001: pp 612-620.

2. Batist et al: Reduced Cardiotoxicity and Preserved Antitumor Efficacy of Liposome-Encapsulated Doxorubicin and Cyclophosphamide (MC) Compared With Conventional Doxorubicin and Cyclophosphamide (standard AC) in a Randomized, Multicenter Trial of Metastatic Breast Cancer. J. Clin. Oncol., 19(5): pp 1444-1454, 2001.

3. Bignazoli et al: Doxorubicin and Paclitaxel (AP) Versus Doxorubicin and Cyclophosphamide (AC) as First-Line Chemotherapy in Metastatic Breast Cancer: The European Organization for Research and Treatment of Cancer 10961 Multicenter Phase III Trial. J. Clin. Oncol., 20(14): pp 3114-3121, 2002.

4. Balducci, L: New Paradigms for Treating Elderly Patients with Cancer: The Comprehensive Geriatric Assessment and Guidelines for Supportive Care. J Support Oncol 2003; 1:30–37.

5. Bear et al: The Effect on Tumor Response of Adding Sequential Preoperative Docetaxel to Preoperative Doxorubicin and Cyclophosphamide (AC): Preliminary Results From National Surgical Adjuvant Breast and Bowel Project Protocol B-27. Journal of Clinical Oncology, 21 (22), 2003: pp 4165-4174.

6. Nabholtz et al: Docetaxel and Doxorubicin (AT) Compared With Doxorubicin and Cyclophosphamide (AC) as First-Line Chemotherapy for Metastatic Breast Cancer: Results of a Randomized, Multicenter, Phase III Trial. Journal of Clinical Oncology, 21 (6), 2003: pp 968-975.

7. Dieras et. al: Randomized Parallel Study of Doxorubicin plus Paclitaxel (AP) and Doxorubicin plus Cyclophosamide (AC) as Neoadjuvant Treatment of Patients with Breast Cancer. J Clin Oncol 22 (24): pp.4958-4965, 2004.

8. Brain et al: Life-Threatening Sepsis Associated With Adjuvant Doxorubicin Plus Docetaxel (AT vs. AC) for Intermediate-Risk Breast Cancer. JAMA. 2005; 293 (19): pp. 2367-2371

9. Gradishar et al: Neoadjuvant docetaxel followed by adjuvant doxorubicin and cyclophosphamide (AC +T vs. AC) in patients with stage III breast cancer. Annals of Oncology 16: pp. 1297–1304, 2005

10. Evans et al: Phase III Randomized Trial of Doxorubicin and Docetaxel (AD) Versus Doxorubicin and Cyclophosphamide (AC) As Primary Medical Therapy in Women With Breast Cancer: An Anglo-Celtic Cooperative Oncology Group Study. J.Clin.Oncol 23 (13): pp. 2988-2995, 2005.

11. Balducci et. al.: Elderly Cancer Patients Receiving Chemotherapy Benefit from Fist-Cycle Pegfilgrastim. The Oncologist 2007;12:1416–1424.

10. Goldstein et al: Concurrent Doxorubicin Plus Docetaxel (AT) Is Not More Effective Than Concurrent Doxorubicin Plus Cyclophosphamide (AC) in Operable Breast Cancer With 0 to 3 Positive Axillary Nodes: North American Breast Cancer Intergroup Trial E 2197. J Clin Oncol 26: pp.4092-4099, 2008.

CERTIFICATION OF SERVICE

The undersigned certifies that on August 7, 2012 a copy of the foregoing **Complaint Under the Federal False Claims Acts and Various State False Claims Acts and the Disclosure Statement** were placed in the United States Mail, Certified Mail/Return Receipt Requested, first class, postage prepaid, addressed to:

Hon. Eric H. Holder, Jr.
Attorney General
U.S. Department of Justice
10th & Constitution Ave., NW
Washington, DC 20530

Heidi A. Wendel
Chief, Civil Frauds Unit
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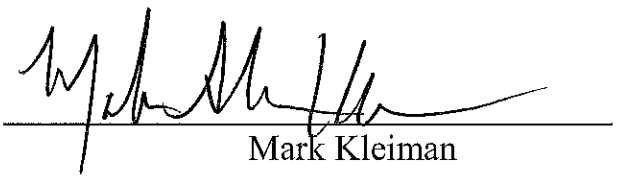

Mark Kleiman